February 25, 1992

MEMORANDUM

SUBJECT: Classification of Castor Oil (Active Ingredient Code 031608) as a Conventional Chemical or as a Biochemical Pesticide

FROM: Robert A. Forrest, Product Manager
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THRU: Reto Engler, Ph.D.
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and

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On February 19, 1992, Dan Peacock of my staff met with the OPP Biotechnology Workgroup to discuss the possibility of considering the new active ingredient, Castor Oil, to be a biochemical and thus reduce the data requirements normally required for a conventional pesticide. See copy of "Chemical Data" report from the Reference File System (REFS). The Workgroup requested that the applicant supply to the Agency additional information before making a decision.

Mr. Peacock has discussed this matter in greater depth with the applicant, Mr. Eldon Pickett, of Mole-Med; with Mr. Raymond Dewberry of the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition; and with [redacted] the applicant's supplier of Castor Oil. With this additional information outlined below, we feel that the Workgroup should be in a position to make a decision on February 26, 1992, as to the status of Castor Oil as a Biochemical:

1) Natural Source (i.e., Castor Bean plant) of Applicant's Castor Oil

In telephone conversations, Mr. Eldon Pickett (the applicant), [redacted] and Mr. Raymond Dewberry (FDA) all confirmed that Castor Oil is derived from seeds of the castor bean plant. According to the Merck Index (8th ed.), under the entry for "Castor Oil" (copy attached), it states that

> Fixed oil obtained by cold-pressing the seed of Ricinus communis L., Euphorbicaceae.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

2) Use of Food Grade Castor Oil in Applicant's Product

The "Product Bulletin" that the applicant submitted from his supplier (copy attached) indicates that their Castor Oil is U.S. Pharmacopeia (USP) grade. According to the applicant's supplier, [redacted] their castor oil exceeds USP grade because additional refining has removed the odor and taste from the oil.

According to FDA's Raymond Dewberry, Castor Oil is listed in the Food Chemical Codex. FDA Regulations (21 CFR 172.876, copy attached) allow Castor Oil to be used as a direct additive (e.g., releasing agent) if the oil meets USP grade. As a drug (i.e. laxative), Mr. Dewberry said that the oil also must meet USP grade.

3) Mode of Action

As indicated by the label (copy attached), the applicant claims that the product is a repellent. He speculates that the mode of action may be as an irritant, rather than as an odor or taste aversant. This idea would be consistent with:

a. Efficacy Data on Target Species

While the applicant has not as yet established the efficacy of the product to the degree required for registration, the company did submit a study (copy attached) on the target species in which the moles disappeared from the test plot while remaining in the control plot.

b. Use of Odorless and Tasteless Grade of Oil

Use of an odorless, tasteless grade of oil would be consistent with a mode of action not dependent on these characteristics.

c. Acute Toxicity Data on the Technical Oil

These data show the active to be virtually non-toxic by the oral route (Category 4) but a mild irritant to the eye.

d. Acute Toxicity Data on the Formulated Product

These data show the formulated product to be virtually non-toxic by the oral route (Cat 4) but an irritant to the skin and eye (Cat 2).

Attachments: 1) Chemistry Data Report (Castor Oil)
2) Merck Index, 8th Ed., pp 218-219
3) CasChem's Product Bulletin for Castor Oil
4) 21 CFR 172.876
5) Mole-Med label (EPA File Symbol 64439-R)
6) Pages from toxicology reports (Technical Product)
7) Pages from toxicology reports (Formulated Product)
8) Efficacy Data

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